REMARKS

Claims 5,9,10,12-14,19-21,39 and 50 are pending in the present application. All claims remain rejected under 35 U.S.C. 101 as lacking utility and under 35 U.S.C.112, first paragraph as failing to comply with the enablement requirement.

SPECIFICATION

The specification is objected to because in the amendment filed January 12, 2004, the cancellation of claims 6-8 was allegedly unclear. Applicant has submitted herewith a complete listing of all claims in the application in compliance with the Revised 37 CFR 1.121, effective July 30, 2003. It is the Applicant's understanding that a clean copy of the claims may not be submitted under the revised amendment practice.

CLAIM REJECTIONS

Rejections under 35 U.S.C. § 101

Claims 5,9,10,12-14,19-21,39 and 50 are rejected under 35 U.S.C. 101 because the claims allegedly lack "patentable utility". Applicants respectfully traverse this rejection. Under 35 U.S.C. 101, Applicant is not required to disclose a "patentable" utility for the invention. What is required is the assertion of a utility that is specific, substantial and credible. Applicant has asserted such a utility for the claimed invention in the specification.

In the previous response, applicant points out that the nucleic acid encoding a polypeptide of SEQ ID NO:13 may be used as a kidney cancer cell marker. Examiner contends that "there is no clear connection between expression of SEQ ID NO:13 and any disease or condition in the part of the application alluded to by the applicants (i.e. pages 237-255)"

Applicants wish to point out that pages 237-255 of the application as filed pertain to the expression of the nucleic acid NOV4 encoding a polypeptide of SEQ ID NO:13 in various

tissues and cell lines. Results obtained from Panel 2D are shown in Table 31 (page 243-245). Description of the tissues in Panel 2D can be found at page 201 and generally is RNA or cDNA isolated from human tissue procured by surgeons working in cooperation with the National Cancer Institute's Cooperative Human Tissue Network or the National Disease Research Initiative. Tissues are from human malignancies and non-cancerous tissue obtained just adjacent to the tumor, or normal adjacent tissue (NAT). Kidney tissue data is presented on page 244. There is a clear pattern of differential gene expression between kidney cancer samples and normal kidney tissue. These results are summarized on page 251 of the specification as follows:

> "Interestingly, expression of this gene is lower in kidney tumors relative to matched normal kidney margins. This pattern of expression is observed in 6/9 of the normal adjacent kidney/kidney cancer pairs on this panel. Thus, expression of the NOV4 gene could be used as a marker to distinguish normal kidney tissue from kidney tumors and may also have diagnostic benefit."

One of skill in the art having read the specification would therefore know to detect the amount of expression of the nucleotide encoding SEQ ID NO:13 in samples of kidney cancer tissue and normal kidney tissue, compare them to each other to help in the differentiation of malignant kidney tissue from normal kidney tissue. As made clear in the specification, in this case it is the lack of expression or a reduced expression of the nucleotide encoding a polypeptide of SEQ ID NO:13 in a kidney tissue that indicates a potentially malignant condition.

This utility is a specific and substantial utility. Applicants have not suggested that NOV4 be used for i.e. "probes" in a general undefined way or for diagnosing an unspecified disease. Applicants have taught that the nucleic acid encoding the polypeptide of SEQ ID NO:13 may be used as a specific target for detecting expression specifically in kidney tissue to differentiate normal kidney tissue from malignant kidney tissue. Furthermore, not any nucleic acid may be utilized; the inventors have shown that specifically NOV4 may be used. If the applicant has made an assertion that the claimed invention is useful for a particular purpose and the assertion would be considered credible by a person of ordinary skill in the art, then a rejection based on lack of utility is not proper. Applicants respectfully request the rejection be withdrawn.

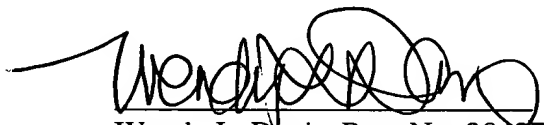
Rejections under 35 U.S.C. § 112, first paragraph

Claims 5,9,10,12-14,19-21, 29 and 50 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully disagree. Applicants submit that as described above, the invention does have at least one asserted utility that is readily apparent based on the teachings of the specification and that requirements under 35 U.S.C. 101 have been met and therefore rejection under 35 U.S.C. 112 first paragraph should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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